

## REMARKS

As a preliminary matter, Applicants' representative thanks Examiner Lundgren for withdrawing the noted § 103 rejections, as stated on page 2 of the Office Action.

Claims 1, 8, and 9 are amended. Claims 21-23 are new. Claims 11-13 have been canceled. After entry of these amendments, Claims 1-10 and 14-23 will be pending in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented on pages 3-6, with an appropriate, defined status identifier, for the convenience of the Examiner. The amendment to Claims 1, 8, and 9, and new Claims 21-23 are fully supported by the application as originally filed, including, but not limited to Claims 12 and 13 as originally filed and also paragraph 55 of the specification.

Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

### I. Rejections Under 35 USC § 112

Claims 1-20 stand rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In particular, the Examiner alleges that the phrases "biochemical blocking compound" and "biochemical blocking layer," and the term "biochemical" are indefinite, in that one of skill in the art could not determine the metes and bounds of the claim based upon the chosen phrasing and terminology. Applicants respectfully traverse this rejection.

Applicants note that Claim 1 currently recites:

A rubbed substrate structure for use in a liquid crystal assay device, comprising:

- (a) a biochemical blocking compound *chemically immobilized on a support* thereby forming a biochemical blocking layer; and
- (b) a biomolecule recognition agent deposited on the same side of the support as the biochemical blocking layer,

wherein the *biochemical blocking compound* is selected from the group consisting of a protein, a zwitterionic polymer, an adsorbed lipid layer, a sugar, a cross-linked lipid, a polyethyleneoxide, a polyoxazoline, and a hydrogel,

wherein a surface of the *biochemical blocking layer* is a *rubbed surface* that possesses features that drive a uniform alignment of liquid crystals when the liquid crystals contact the rubbed surface,

wherein the *biochemical blocking layer* resists *non-specific adsorption* of non-target species, and

further wherein the biomolecule recognition agent comprises a recognition site capable of selectively recognizing a target species.

Applicants submit that the phrase “biochemical blocking compound” is definite and clear in view of the definitions within the claim itself as to structure and function of the biochemical blocking compound and its use in the formation of the biochemical blocking layer. As defined, the meaning of the disputed phrase is clear; a biochemical blocking compound is a compound that blocks biochemicals.

The structure of the biochemical blocking compound is provided by the listing of individual materials from which the biochemical blocking compound is selected. The listing includes proteins, zwitterionic polymers, adsorbed lipid layers, sugars, cross-linked lipids, polyethyleneoxide, polyoxazolines, and hydrogels.

The function of the biochemical blocking compound is provided by the phrase stating that the biochemical blocking layer (i.e. formed from the biochemical blocking compound) resists non-specific adsorption of non-target species.

Paragraphs 52-72 of the specification, lend additional clarity and definition to the biochemical blocking compound, biochemical blocking layer, and recognition agent:

[0052] Rubbed biochemical blocking layers such as rubbed BSA resist the non-specific adsorption of other species such as proteins. Additionally, a rubbed substrate containing such a rubbed blocking layer provides uniform alignment of liquid crystals which can be disrupted when a target species binds to a biomolecule recognition agent on the surface.

[0053] Rubbed substrate structures for use in liquid crystal assay devices generally include a biochemical blocking compound immobilized on the surface of at least one side of a support. The immobilization of the biochemical blocking compound on the support forms a biochemical blocking layer on the support.

[0055] Various materials such as, but not limited to, serum albumins, zwitterionic polymers, adsorbed lipid layers, dextran and other sugars, cross-linked lipids, polyethyleneoxide, polyoxazolines, and hydrogels may be suitable for use as biochemical compounds for use in the biochemical blocking layer. Preferred materials for use as biochemical blocking compounds include serum albumins such as, but not limited to, bovine serum albumin, human serum albumin, rodent serum albumin, canine serum albumin, feline serum albumin, porcine serum albumin, equine serum albumin, and rabbit serum albumin. Bovine serum albumin is a particularly preferred biochemical blocking compound for use in forming a biochemical blocking layer in a rubbed substrate structure according to the present invention.

[0056] A rubbed substrate structure for use in a liquid crystal assay device preferably includes a biomolecule recognition agent which is deposited on a side of the support that contains the biochemical blocking layer. The biomolecule recognition agent includes a recognition site capable of recognizing and preferably binding a target species to be detected by the liquid crystal assay device if the target species is present in a sample.

[0072] The biochemical blocking layer resists the non-specific adsorption of non-target species. Any non-specific adsorption of non-target species that does occur, does not change in the orientation of a liquid crystal on the surface such that it prevents the interpretation of the orientation of the liquid crystal so as to infer the binding of the targeted species. For example, rubbed substrate structures on silicon wafers or glass slides containing a biochemical blocking layer formed from bovine serum albumin resisted the non-specific adsorption of fibrinogen, lysozyme, anti-FITC, and anti-streptavidin. This important characteristic of the biochemical blocking layer is important in rubbed substrate structures for employment in liquid crystal assay devices because non-specific adsorption of non-target species would disrupt the uniform anchoring of liquid crystals brought into contact with the surface which would result in a false positive test result. A particularly preferred biochemical blocking layer contains BSA which resists non-specific adsorption, has numerous cites for attachment of biomolecule recognition agents, reacts easily with

activated surfaces of supports, and rubs to produce uniform anchoring of liquid crystals such as 5CB.

Thus, the device is well defined and clear as recited in Claim 1. Claim 1 recites a rubbed substrate structure that includes a biochemical compound that forms the biochemical blocking layer, and a biomolecule recognition agent. "The biomolecule recognition agent includes a recognition site capable of recognizing and preferably binding a target species." Paragraph 56. All of these elements work in concert with the biomolecule recognition agent binding a target species, indicated by an observable change in orientation of the liquid crystal, while the biochemical blocking layer prevents the absorption of non-target species. As the device is exposed to a sample, non-target species are deflected from the surface, with the liquid crystal not being disturbed, thereby no indication of a target species is observed. When a target species is present in the sample, the recognition agent binds the species, thereby disrupting the alignment of the liquid crystal, leading to an observation of this event.

The biochemical blocking layer is formed by the immobilization of the biochemical blocking compound on the substrate. The biochemical blocking layer prevents biochemicals (i.e. non-target species) from adsorbing to the surface and causing a "false positive" test, while the recognition agent binds those biochemicals (i.e. target species) of interest. As such, Applicants assert that the claims are definite and well supported by the specification as filed.

Applicants submit that the structure and function of the biochemical blocking compound and the biochemical blocking layer are defined within the claim and further definition is provided by the specification and examples. As such, Applicants respectfully request that the Examiner reconsider and remove the noted §112 rejections and allow the application to move forward to issuance.

## **II. Claim Rejections Under 35 USC § 102**

Claims 1, 2, 4, 6, 7, and 14-20 stand rejected under 35 USC §102(b) as being anticipated by U.S. 6,284,197, issued to Abbott *et al.* Applicants respectfully traverse this rejection.

In rejecting the claims over Abbott, the Examiner has shown that Abbott teaches that the “surface of the substrate...is patterned with features such as grooves and ridges with emphasis on the texture [citation to Abbott, col. 16, lines 47-57] [and that]...Abbott generally identifies certain techniques for creating these features [citing to Abbott, col. 17, lines 7-18].” Office Action, page 4. Abbott also teaches that the patterning of the “surface of the substrate...by rubbing,...grooving,..., or other similar techniques [is] known to those of skill in the art.” Col. 16, lines 47-57. The Examiner has even added emphasis to these portions. The Examiner also points to Abbott as teaching that “the surface has been prepared by rubbing,” and the Examiner has again emphasized these portions. Office Action, page 5. Applicants point out that the “surface,” emphasized by the Examiner is the *surface of the substrate* **not** a layer or biochemical blocking compound deposited on the surface of the substrate.

Applicants assert that Abbott does not anticipate the claimed invention, either expressly or inherently. Abbott teaches exactly what the Examiner has alleged: the patterning of the *surface of the substrate*. Such a claim is not anticipatory of the rubbing of the surface of the biochemical blocking layer, as is recited in instant claim 1. The surface of the substrate and the surface of the biochemical blocking layer are not the same surface and rubbing of one is not anticipatory or obviating of the other. It will be noted that claim 1, the only independent claim, recites, in part:

A rubbed substrate structure for use in a liquid crystal assay device, comprising:

(a) a biochemical blocking compound chemically immobilized on a support thereby forming a biochemical blocking layer; and...

wherein a *surface of the biochemical blocking layer* is a rubbed surface that possesses features that drive a uniform alignment of liquid crystals when the liquid crystals contact the rubbed surface...

(Emphasis added).

The claim clearly states that it is the surface of the biochemical blocking layer that is rubbed. Abbott clearly states that it is the surface of the substrate that is rubbed. These are different surface and the Abbott reference cannot be anticipating of the claim as presented.

Applicants also submit that Abbott is not inherently anticipatory of the instantly claimed invention. For a reference to inherently anticipate a claim, the claimed invention must necessarily flow from the reference:

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

(M.P.E.P § 2112(IV), Emphasis in original.)

As shown by the Examiner, Abbott teaches the rubbing of a surface prior to the deposition of a blocking layer, but from this teaching it does not necessarily flow that the rubbing of the surface of the substrate will drive the uniform alignment of liquid crystals after a biochemical blocking layer has been deposited on the rubbed substrate. In fact, Applicants have already shown that rubbing of the substrate does not provide the same results as rubbing of the biochemical blocking layer. Applicants direct the Examiner's attention to the Abbott Declaration filed with their response of October 20, 2006, where these differences are further elucidated.

For at least these reasons, Applicants submit that Abbott fails to teach each and every element of the claims as presented, and as such Abbott is not anticipatory of the rejected claims. Applicants respectfully request that Examiner Lundgren withdraw the rejections under 35 USC § 102 and allow the application to move forward to issuance.

### III. ODP Rejections

Claims 1, 8, 9, 11, 12, 16 and 20 stand provisionally rejected under the doctrine of judicially created obviousness-type double patenting over claims 1, 8-10, and 14 of co-pending Application No. 10/934,023. As of May 15, 2007, USSN 10/934,023 was still pending, and thus, the rejection of claims 1, 8, 9, 11, 12, 16 and 20 remains provisional.

Applicants respectfully submit that the procedure set forth in § 804(I)(B)(2) of the M.P.E.P. is applicable to the present provisional double-patenting rejection. Section 804(I)(B)(2) of the M.P.E.P. requires that

[i]f a 'provisional' statutory double patenting rejection is the only rejection remaining in one of the applications (but not both), the examiner should withdraw the rejection in that application and permit the application to issue as a patent, thereby converting the 'provisional' double patenting rejection in the other application into a double patenting rejection when the application issues as a patent.

Because Applicants believe that, after consideration of this reply, no other rejections shall remain in the present application, Applicants respectfully request that Examiner Tran withdraw the provisional double patenting rejection of claims 1, 8, 9, 11, 12, 16 and 20 in the present application, based on claims 1, 8-10, and 14 of co-pending USSN 10/934,023, and allow this application to issue. Applicants make no admission regarding the propriety of the double patenting rejection in this application over USSN 10/934,023 and specifically reserve the right to challenge the propriety of this rejection.

#### CONCLUSION


Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. After entry of the instant reply, if Examiner Lundgren has any remaining concerns regarding the patentability of the presently claimed invention over the cited art, he is invited to contact the undersigned by telephone to discuss such concerns.

Respectfully submitted,

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